

**INSTRUCTIONS FOR PROGRAM MANAGERS****Don't forget to Delete this Instruction Section from your final Order!**

A) This Boilerplate Order contains Instructional Notes to Program Managers throughout the text. The notes are in red and bold type in the text to make them easy to find. When the Order is completed make certain that all these notes have been deleted. To ensure that all notes are deleted, use "Edit, Find and Replace" to perform a global search for "[**Note to Program Managers:**".

**B) Respirator Table Appendices**

This Boilerplate Order has two Appendices containing Respirator Tables.

**Appendix 1: Protection in the Workplace Respirators**

Appendix 1 contains tables of respirators for inclusion in the Protection in the Workplace section of the Order.

1. **Copy** the appropriate individual respirator(s) from Appendix 1.
2. **Paste** the respirator(s) in the Protection of the Workplace section of the Order (a Note to Program Managers shows you where).
3. **Delete** the remainder of Appendix 1.

**Appendix 2: NCELS Respirators**

Appendix 2 contains tables for the NCELS section of the Order.

1. **Copy** the appropriate complete respirator table from Appendix 2.
2. **Paste** the respirator table in the NCELS section of the Order (a Note to Program Managers shows you where).
3. **Delete** the remainder of Appendix 2.

Do **Not** Delete Attachments A, B, and C.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

)

Premanufacture Notice Number:

)

)

)

)

)

)

\_\_\_\_\_

)

\_\_\_\_\_

)

)

)

)

---

Consent Order and Determinations Supporting Consent Order

---

## TABLE OF CONTENTS

### Preamble

- I. Introduction
- II. Summary of Terms of the Order
- III. Contents of PMN
- IV. EPA's Assessment of Exposure and Risk
- V. EPA's Conclusions of Law
- VI. Information Required to Evaluate Human Health and Environmental Effects

### Consent Order

- I. Scope of Applicability and Exemptions
- II. Terms of Manufacture, Import, Processing, Distribution in Commerce, Use, and Disposal Pending Submission and Evaluation of Information
- III. Recordkeeping
- IV. Requests for Pre-Inspection Information
- V. Successor Liability Upon Transfer of Consent Order
- VI. Modification and Revocation of Consent Order
- VII. Effect of Consent Order

Attachment A - Definitions

Attachment B - Statistical Analysis of NCELS Analytical Method Verification Results

Attachment C - Pollution Prevention Plan Guidance

Attachment D - Notice of Transfer of Consent Order

## PREAMBLE

### I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act (“TSCA”) (15 U.S.C. 2604(e)), the Environmental Protection Agency (“EPA” or “the Agency”) issues the attached Order, regarding premanufacture notice (“PMN”) P-\_\_\_\_\_ for the chemical substance \_\_\_\_\_ (“the PMN substance”) submitted by \_\_\_\_\_ (“the Company”), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. (In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.).

### II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

COMMENT 2/6/08 10:11 AM  
Comment: [DELETE INAPPLICABLE  
ENTRIES; LETTER REMAINING ENTRIES  
WITH LOWER CASE LETTERS]

( ) submit to EPA a Pollution Prevention Plan within one year from the date of commencement of non-exempt commercial manufacture of the PMN substance,

( ) submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a

total of \_\_\_\_kilograms of the PMN substance;

( ) provide its workers personal protective equipment to prevent dermal exposure;

( ) provide its workers respirators to prevent inhalation exposure;

( ) as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substance at or below a specified New Chemical Exposure Limit (“NCEL”) of \_\_\_\_\_, verified by actual exposure monitoring data (To pursue this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA.);

( ) label the PMN substance and provide Material Safety Data Sheets (“MSDS”) and worker training in accordance with the provisions of the Hazard Communication Program section;

( ) not manufacture the PMN substance \_\_\_\_\_;

( ) not process the PMN substance \_\_\_\_\_;

( ) not use the PMN substance \_\_\_\_\_;

( ) distribute the PMN substance only to a person who agrees to follow the same restrictions

(except the testing requirements) and to not further distribute the PMN substance until it has been completely reacted;

( ) distribute the PMN substance only \_\_\_\_\_;

( ) dispose of the PMN substance only by \_\_\_\_\_;

( ) comply with the Release to Water provisions; and,

( ) maintain certain records.

### **III. CONTENTS OF PMN**

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Chemical Identity:

Specific:

Generic:

Use:

Specific:

Generic:

Maximum 12-Month Production Volume:

Test Data Submitted with PMN:

#### **IV. EPA'S ASSESSMENT OF RISK**

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

##### Human Health Effects Summary:

Absorption:

Toxicological Endpoints of Concern:

Basis:

**[Note to Program Managers: If concern for the PMN substance is based on a chemical category of concern, include the following reference to the New Chemicals Chemical Category Website.]**

See [www.epa.gov/opptintr/newchemicals/pubs/chemcat.htm](http://www.epa.gov/opptintr/newchemicals/pubs/chemcat.htm)

##### Environmental Effects Summary:

**[Note to Program Managers: If concern for the PMN substance is based on a chemical category of concern, include the following reference to the New Chemicals Chemical Category Website.]**

See [www.epa.gov/opptintr/newchemicals/pubs/chemcat.htm](http://www.epa.gov/opptintr/newchemicals/pubs/chemcat.htm)

##### Exposure and Environmental Release Summary:

	Manufacture	Process	Use	Consumer
--	-------------	---------	-----	----------

# Sites				
Workers (#/site)				
Exposure (days/year)				
Dermal Exposure (mg/day)				
Inhalation Exposure (mg/day)				
Drinking Water Exposure (mg/day)				
Releases (days/year)				
Release to Water (kg/day)				
Surface Water Concentration (ppb)				
Days Exceeding Concern Level				

Risk to Workers:

**[Note to Program Managers: Give statement on MOE or cancer risk.]**

NIOSH Assigned Protection Factor (“APF”):

New Chemical Exposure Limit: \_\_\_\_ as an 8-hour time-weighted average (“TWA”).

Risk to General Public:

Risk to Consumers:

#### **V. EPA’S CONCLUSIONS OF LAW**

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for \_\_\_\_\_

\_\_\_\_\_

from exposure of humans and aquatic organisms to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

(b) In light of the potential risk of \_\_\_\_\_

posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that

uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

COMMENT 2/6/08 10:11 AM

**Comment:** [CITE PARAGRAPH C. BELOW ONLY IF THE EXPOSURE-BASED HEALTH CRITERIA ARE ALSO MET]

(c) In light of the estimated production volume of, and human exposure to the PMN substance, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.

## **VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS**

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The following additional information would be required to evaluate the following effects which may be caused by the PMN substance:

<u>Information</u>	<u>Effects</u>	<u>Guidelines</u>
--------------------	----------------	-------------------

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing,

distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

COMMENT 2/6/08 10:11 AM

**Comment:** [DELETE THOSE ACTIVITY RESTRICTIONS WHICH ARE NOT DEPENDENT UPON THE PENDING TESTING. FOR EXAMPLE, IF THE PENDING TESTING IS FOR ECOTOXICITY, THEN THE ONLY ACTIVITY RESTRICTIONS WHICH WILL REMAIN IN EFFECT PENDING THAT TESTING AND SHOULD BE LISTED HERE ARE THE DISPOSAL RESTRICTIONS.]

### **POLLUTION PREVENTION PLAN**

(a) Pollution Prevention Plan. The Pollution Prevention Act of 1990 (42 USC 13101) and EPA's Pollution Prevention Strategy (56 FR 7849; Feb. 26, 1991) establish an environmental management hierarchy that ranks risk education methods in the following order or preference: source reduction first, recycling second, treatment third, and disposal last. To promote this policy, the Company shall prepare a written Pollution Prevention Plan to identify and evaluate alternative methods of handling the new chemical substance during its full life-cycle (including manufacture, processing, use, distribution, and disposal) that may avoid unnecessary human exposures and/or environmental releases of the PMN substance. (To assist the Company in preparation of its Pollution Prevention Plan, non-binding guidance is provided in Attachment C). Within one year from the date of commencement of non-exempt commercial manufacture of the PMN substance, the Company shall submit to EPA a signed and dated copy of the completed Pollution Prevention Plan. Once the Company has prepared and submitted the Pollution Prevention Plan to EPA, the Company shall provide a copy (or relevant summary) of the Pollution Prevention Plan to any person outside the Company to whom the Company subsequently distributes the PMN substance.

## CONSENT ORDER

### **I. SCOPE OF APPLICABILITY AND EXEMPTIONS**

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance \_\_\_\_\_ (P- \_\_\_\_ - \_\_\_\_\_) (“the PMN substance”) in the United States by \_\_\_\_\_ (“the Company”), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured) or \_\_\_\_\_.

**[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]**

(2) De Minimis Concentrations. The requirements of this Order do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration (“TWA”) or in-stream concentration (“N”) less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(3) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as “solely for export” even if some amount of

the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(4) Research & Development (“R&D”). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36.

(5) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a “byproduct” as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(6) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption (“TME”) under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption (“LVE”) or Low Release and Exposure Exemption (“LoREX”) under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

**II. TERMS OF MANUFACTURE, IMPORT, PROCESSING,  
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL  
PENDING SUBMISSION AND EVALUATION OF INFORMATION**

**PROHIBITION**

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects **[Note to Program Managers: Edit as appropriate.]** of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

**TESTING**

**(a) Section 8(e) Reporting.** Any information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

COMMENT 2/6/08 10:11 AM

**Comment:** [INCLUDE PARAGRAPHS (a), (b) and (c) IN ALL ORDERS. INCLUDE THE ENTIRE TESTING SECTION IN ANY ORDERS WITH TRIGGERED TESTING. THE CORRESPONDING SNUR CITATION FOR TRIGGERED TESTING IS THE PRODUCTION VOLUME LIMIT AT 721.80(P) FOR NON-CBI PRODUCTION VOLUMES AND 721.80(q) FOR CBI VOLUMES. IN ADDITION, FOR THE SNUR, YOU MUST SPECIFY THE SNUR PRODUCTION VOLUME LIMIT. FOR TIERED TESTING, THE SNUR VOLUME LIMIT SHOULD BE THE LOWEST PRODUCTION VOLUME IN PARAGRAPH (d) OF THE CONSENT ORDER TESTING SECTION.]

COMMENT 2/6/08 10:11 AM

**Comment:** - [NA]

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

- (1) The date when the study is scheduled to commence;
- (2) The name and address of the laboratory which will conduct the study;
- (3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,
- (4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes (“the production limits”), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit

Study

Guideline

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data (“the report and data”) to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable “Reporting,” “Data and Reporting,” and “Test Report” subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word “should” in those subparagraphs shall be interpreted to mean “shall” to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.80(p) for NON-CBI]  
[721.80(q) for CBI]

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph

(e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the

Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

### **PROTECTION IN THE WORKPLACE**

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Company must establish a program whereby:

COMMENT 2/6/08 10:11 AM

**Comment:** [NOTE: THERE ARE SEVERAL PARAGRAPH CROSS REFERENCES IN THIS SECTION (SEE "[CHECK]" INDICATORS) WHICH WILL HAVE TO BE CHANGED IF ANY OF THE PARAGRAPHS IN THIS SECTION ARE DELETED. IF PARAGRAPH DESIGNATIONS CHANGE DUE TO DELETIONS, DO NOT MAKE THE CORRESPONDING DESIGNATION CHANGES IN THE SNUR -- SNUR CITATIONS NEVER CHANGE.]

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

COMMENT 2/6/08 10:11 AM

**Comment:** [THE FOLLOWING WILL BE THE STANDARD SUBPARAGRAPH TO CITE WHENEVER DERMAL PROTECTION IS REQUIRED. NOTE THAT IT IS A "PERFORMANCE-BASED" REQUIREMENT - THAT IS, IT REQUIRES THE COMPANY TO MEET A PERFORMANCE GOAL (PREVENTING DERMAL EXPOSURE) BUT DOES NOT SPECIFY A SPECIFIC CONTROL TECHNOLOGY (E.G., GLOVES) TO MEET THAT GOAL. THE COMPANY IS FREE TO CHOOSE THE FORM OF CONTROL TECHNOLOGY TO EMPLOY SO LONG AS THE PERFORMANCE GOAL IS ACHIEVED].

COMMENT 2/6/08 10:11 AM

**Comment:** [CHECK]

**[Note to Program Managers: Use Paragraph (a)(2) when the PMN substance may present a high dermal risk and you want to specifically require certain types of dermal protective equipment. If the dermal risk is only moderate or general, paragraph (a)(1) alone may suffice and you can delete (a)(2).]**

(2) Specific Dermal Protective Equipment. The dermal personal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

- (i) Gloves.
- (ii) Full body chemical protective clothing.
- (iii) Chemical goggles or equivalent eye protection.
- (iv) Clothing which covers any other exposed areas of the arms, legs and torso.

(3) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.63(a)(1)]

COMMENT 2/6/08 10:11 AM

**Comment:** [ITEMS (i), (ii), AND (iii) OF THE FOLLOWING SUBPARAGRAPH MAY BE ADDED TO THE REQUIREMENTS OF PARAGRAPH (1) ABOVE IF THE AGENCY BELIEVES THAT A PARTICULAR CONTROL TECHNOLOGY IS ESSENTIAL FOR THE PROTECTION OF WORKERS, E.G., CHEMICAL GOGGLES WOULD BE MANDATED FOR A SUBSTANCE WHICH IS SUSPECTED OF BEING SEVERELY TOXIC VIA THE OCULAR ROUTE. ITEM (iv) IS TO BE ADDED WHERE DERMAL EXPOSURE IS NOT OF SUFFICIENT CONCERN TO WARRANT PERMEABILITY TESTING OF PROTECTIVE CLOTHING. FOR MORE CASES, HOWEVER, PARAGRAPH (2) SHOULD BE INCLUDED!!!]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.63(a)(2)(i)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [723.63(a)(2)(ii)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.63(a)(2)(iii)]

prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials (“ASTM”) F739 “Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases.” Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 “Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials.” Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer’s Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this

COMMENT 2/6/08 10:11 AM

Comment:  
[721.63(a)(3)]

COMMENT 2/6/08 10:11 AM

Comment: [CHECK]

section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of \_\_\_\_\_, from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(5) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

COMMENT 2/6/08 10:11 AM  
Comment: [721.63(a)(4)]

- (i) Particulate (including solids or liquid droplets),
- (ii) Gas/vapor (all substances in the gas form), or
- (iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states

are both present; a good example is paint spray mist, which contains both liquid droplets and vapor).

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section:

COMMENT 2/6/08 10:11 AM  
Comment: [721.63(a)(6)(vi)]

**[Note to Program Managers: Copy the appropriate individual respirator(s) from the list in Appendix 1 of this document, past them here, then delete Appendix 1.]**

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

### **NEW CHEMICAL EXPOSURE LIMIT**

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling

inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substance by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the PMN substance, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and,

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substance by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit (NCEL) for the PMN substance is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substance is as follows:

(i) Time-Weighted Average (“TWA”) Limit. The Company shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of \_\_\_\_\_ (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section. \_\_\_\_\_

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift (NCEL<sub>n</sub>) shall be determined by the following equation:  $NCEL_n = NCEL \times (8/n) \times [(24-n)/16]$ , where n = the number of hours in the actual work-shift.

(iii) Short-Term Exposure Limit (“STEL”). The Company shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of \_\_\_\_\_ as averaged over any 15 minute period, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

(2) Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit (PEL) specifically applicable to this PMN substance and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any

COMMENT 2/6/08 10:11 AM

**Comment:** For PMNs which are not expected to cause acute toxicity, delete the short-term exposure limit (STEL) requirements in paragraphs (b)(1)(ii) and (d)(1)(v).

requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL shall automatically become null and void. However, the requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the PMN substance.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical method for the PMN substance, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(B), (4)(v)(B), (8), and (9). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substance which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN # \_\_\_\_\_," after-which the correct PMN number for this chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company shall have an independent reference laboratory (“Laboratory”) verify the validity of the analytical method for the PMN substance, in accordance with the other requirements in this subsection (c)(3). It is the Company’s responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substance must comply with TSCA Good Laboratory Practice Standards (“GLPS”) at 40 CFR Part 792. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 (“Test system care facilities”), 792.45 (“Test system supply facilities”) and 792.90 (“Animal and other test system care”), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association (“AIHA”) Industrial Hygiene Laboratory Accreditation Program (“IHLAP”); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company shall collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or “glove box”) which closely resembles the

actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or “glove box”) which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company, and the other shall be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment B - Statistical Analysis of NCELS Analytical Method Verification Results.) The average of each set of six samples must be within 10% of the true value. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the true value.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, shall be accurate to within  $\pm 25\%$  at a 95% confidence level for concentrations of the PMN substance ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substance across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal

that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL ( $0.5 \times \text{NCEL}$ ); between one half and one times the NCEL ( $0.5 \times \text{NCEL} < > 1 \times \text{NCEL}$ ); one times the NCEL ( $1 \times \text{NCEL}$ ); between one and two times the NCEL ( $1 \times \text{NCEL} < > 2 \times \text{NCEL}$ ), and twice the NCEL ( $2 \times \text{NCEL}$ ).

(II) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company shall conduct both an initial instrument calibration and a continuing calibration. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall within  $\pm 25\%$  of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Company must calculate the percent of the PMN substance recovered by the analytical method from a sample containing a known quantity of the PMN substance. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or “glove box”) which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substance onto a sample collection device. (Such a sample is referred to as a “matrix spike”). The calculated percent recovery for each matrix spike shall be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substance must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substance onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device’s capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substance is

detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substance at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m<sup>3</sup> and the percent recovery is 75%, use the value  $30 \text{ mg/m}^3 / (0.75) = 40 \text{ mg/m}^3$  when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs (c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive PMN substance; or introduction of water/increased humidity to the workplace which could react with the PMN substance and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The “action level” is defined as an airborne concentration of the PMN substance, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to

one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company shall take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substance would be if respirators were not worn. The Company shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an “exposure group”) where inhalation exposure to the PMN substance is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 (“Test system care facilities”), 792.45 (“Test system supply facilities”) and 792.90 (“Animal and other test system care”), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either:

(A) the American Industrial Hygiene Association (“AIHA”) Industrial Hygiene Laboratory Accreditation Program (“IHLAP”); or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for each exposure group.

(v) STEL Samples. Determinations of compliance with the STEL shall be made from 15 minute breathing zone samples measured at operations where there is reason to believe that the maximum short-term exposures will occur, such as during, but not limited to, the following operations: \_\_\_\_\_. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

COMMENT 2/6/08 10:11 AM

**Comment:** For PMNs which are not expected to cause acute toxicity, delete the short-term exposure limit (STEL) requirements in paragraphs (b)(1)(ii) and (d)(1)(v).

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substance for each exposure group in which persons are reasonably likely to be exposed to the PMN substance.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substance is not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture,

processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substance is not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 3 month period does not constitute grounds for postponement of the 3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5)

of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substance; and,

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the PMN substance.

(ii) In no event is the additional exposure monitoring requirement in paragraph

(d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action.

During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the PMN substance will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific “exposure group” (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure

Limit section (except paragraph (d)(5) “Additional Monitoring” and subsection (f) “NCEL Record-keeping”) and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substance and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Company’s current workplace operations with the PMN substance. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substance, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substance for any person who is reasonably likely to be exposed to the PMN substance by inhalation exceeds the NCEL, the Company shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the PMN substance at a workplace in accordance with this New Chemical Exposure Limit section, the Company shall comply with the respirator requirements in the Protection in the Workplace section of this Order

at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substance by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

**[Note to Program Managers: Copy the appropriate complete table from the Table of Respirators for NCELs in Appendix 2, paste it here, then delete Appendix 2.]**

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the lower quantitation limit (“LQL”) of the analytical method (as described in paragraph (c)(4)(ii)) is measured, the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the actual upper quantitation limit (“UQL”) of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company shall maintain the following records until 30 years after the date they are

created, and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the American Industrial Hygiene Association (“AIHA”) or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substance;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

#### **HAZARD COMMUNICATION PROGRAM**

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written

COMMENT 2/6/08 10:11 AM

**Comment:** [THIS SECTION HAS BEEN MODIFIED SIGNIFICANTLY FROM THE OLD ORDERS TO ACHIEVE GREATER UNIFORMITY WITH OSHA'S HAZARD COMMUNICATION STANDARD ("HCS"). PARAGRAPHS (a) - (d) AND (f) SHOULD BE CITED IN THEIR ENTIRETY FOR ALL RISK-BASED ORDERS. IF THE PARAGRAPH (e) EXEMPTION FOR LOW CONCENTRATION MIXTURES IS DELETED FROM THIS SECTION, ALL CROSS REFERENCES FOLLOWED BY THE INDICATOR "[CHECK]" SHOULD BE RELETTERED ACCORDINGLY.]

program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 C.F.R. Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

COMMENT 2/6/08 10:11 AM  
Comment: [721.72(a)]

(b) Labeling.

(1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(I) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (f) of this section or by the Company, for the PMN substance.

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(II) The identity by which the PMN substance may be commonly recognized.

(III) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Company, for the PMN substance.

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(IV) A statement of exposure and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Company, for the PMN substance.

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace

for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(I) The information prescribed in subparagraph (b)(1)(i) of this section.

(II) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a “hazardous chemical” under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures

pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

COMMENT 2/6/08 10:11 AM  
Comment: [721.72(b)]

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

COMMENT 2/6/08 10:11 AM  
Comment: [CHECK]

(v) Signs and symptoms of exposure, and any medical conditions which are

expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures. The MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of the New Chemical Exposure Limit section of this Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS,

the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily

accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages. \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment:  
[721.72(c)]

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) \_\_\_\_\_ of this section.

COMMENT 2/6/08 10:11 AM

Comment: [CHECK]

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

COMMENT 2/6/08 10:11 AM  
Comment: [721.72(d)]

(e) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

COMMENT 2/6/08 10:11 AM  
Comment: [CITE THE APPROPRIATE LANGUAGE FROM THE FOLLOWING; DELETE THE REST AND RELETTER/NUMBER AS APPROPRIATE]

(1) Human health hazard statements. This substance may cause:

- (i) skin irritation.
- (ii) respiratory complications.
- (iii) central nervous system effects.

COMMENT 2/6/08 10:11 AM  
Comment: [721.72(g)(1)(i)]

COMMENT 2/6/08 10:11 AM  
Comment: [721.72(g)(1)(ii)]

(iv) internal organ effects.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(iii)]
(v) birth defects.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(iv)]
(vi) reproductive effects.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(v)]
(vii) cancer.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(vi)]
(viii) immune system effects.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(vii)]
(ix) developmental effects.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(viii)]
(2) Human hazard precautionary statements. When using this substance:	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(1)(ix)]
(i) avoid skin contact.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(2)(i)]
(ii) avoid breathing the substance.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(2)(ii)]
(iii) avoid ingestion.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(2)(iii)]
(iv) use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of _____. <b>[Note to Program Managers: Add STEL if applicable.]</b>	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(2)(iv)]
(v) use skin protection.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(2)(v)]
(3) Environmental hazard statements. This substance may be:	
(i) toxic to fish.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(3)(i)]
(ii) toxic to aquatic organisms.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(3)(ii)]
(4) Environmental hazard precautionary statements. Notice to users:	
(i) disposal restrictions apply.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(4)(i)]
(ii) spill clean-up restrictions apply.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(4)(ii)]
(iii) do not release to water.	COMMENT 2/6/08 10:11 AM Comment: [721.72(g)(4)(iii)]
(5) The human and environmental hazard and precautionary statement on the label	COMMENT 2/6/08 10:11 AM Comment: [ALL ORDERS:]

prepared pursuant to paragraph (b) of this section must be followed by the statement: “See the MSDS for details.”

COMMENT 2/6/08 10:11 AM

Comment: [721.72(g)(5)]

## MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

COMMENT 2/6/08 10:11 AM

Comment: [INCLUDE PARAGRAPH (a) IN ALL ORDERS. THERE IS NO CORRESPONDING SNUR PROVISION FOR PARAGRAPH (a).]

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule (“SNUR”) governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture the PMN substance:

(1) In non-enclosed processes;

(2) In the United States;

(3) Beyond an aggregate manufacture and importation volume of \_\_\_\_\_;

(4) Beyond an annual manufacture and importation volume of \_\_\_\_\_;

COMMENT 2/6/08 10:11 AM

Comment: [MAKE SURE PUNCTUATION IS CORRECT IN FOLLOWING SECTIONS]

COMMENT 2/6/08 10:11 AM

Comment: [721.80(b)]

COMMENT 2/6/08 10:11 AM

Comment: [721.80(f)]

COMMENT 2/6/08 10:11 AM

Comment: [INSERT VOLUME IN SNUR]  
[non-CBI] [721.80(p)]  
[CBI] [721.80(q)]

COMMENT 2/6/08 10:11 AM

Comment: [INSERT VOLUME [non-CBI] [721.80(s)]  
IN SNUR] [CBI]  
[721.80(t)]

(5) In the form of a powder;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(w)(1)]

(6) In the form of a solid;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(w)(2)]

(7) In the form of a liquid;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(w)(3)]

(8) In the form of a gas; or|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(w)(4)]

(9) Other: \_\_\_\_\_.

### **PROCESSING**

(a) The Company shall not process the PMN substance:

(1) In non-enclosed processes;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(c)]

(2) Beyond the site of manufacture or import;|

COMMENT 2/6/08 10:11 AM

Comment:  
[721.80(c)]

(3) In the form of a powder;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(x)(1)]

(4) In the form of a solid;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(x)(2)]

(5) In the form of a liquid;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(x)(3)]

(6) In the form of a gas; or|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(x)(4)]

(7) Other:\_\_\_\_\_.

### **USE**

(a) The Company shall not use the PMN substance:

(1) In non-enclosed processes;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(a)]

(2) Beyond the site of manufacture or import;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(d)]

(3) Other than as an intermediate;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(g)]

(4) Other than as a site-limited intermediate;|

COMMENT 2/6/08 10:11 AM

Comment: . [721.80(h)]

(5) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds \_\_\_\_ percent; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(i)]

(6) Other than as described in the PMN; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(j)]

(7) For non-industrial applications; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(l)]

(8) For commercial applications; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(m)]

(9) For non-commercial applications; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(n)]

(10) In consumer products; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(o)]

(11) In the form of a powder; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(v)(1)]

(12) In the form of a solid; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(v)(2)]

(13) In the form of a liquid; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(v)(3)]

(14) In the form of a gas; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(v)(4)]

(15) Involving an application method that generates a vapor, mist, or aerosol; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(y)(1)]

(16) Involving an application method that generates a dust; or \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(y)(2)]

(17) Other: \_\_\_\_\_

COMMENT 2/6/08 10:11 AM  
Comment: . [721.80(k)]

### **DISTRIBUTION**

(a) Export Notice Requirement. Prior to the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information:

(1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or

COMMENT 2/6/08 10:11 AM  
Comment: [ALWAYS INCLUDE SUBPARAGRAPH (a)(1) UNLESS THERE IS A GOOD REASON NOT TO INCLUDE IT! THERE ARE NO CORRESPONDING SNUR CITATIONS FOR THE PROVISIONS IN THIS DISTRIBUTION SECTION.]

(B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. (i) Except after the PMN has been completely reacted (or \_\_\_\_\_), **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]** or as provided in paragraph (b), the Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or \_\_\_\_\_. **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]**

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order,

COMMENT 12/4/08 1:00 PM

**Comment:** [ALWAYS INCLUDE SUBPARAGRAPH (b)(2) UNLESS THERE IS A GOOD REASON NOT TO INCLUDE IT! THERE ARE NO CORRESPONDING SNUR CITATIONS FOR THE PROVISIONS IN THIS DISTRIBUTION SECTION.]

or \_\_\_\_\_.

(4) Comply with the same requirements and restrictions, if any, required of the Company in the Hazard Communication Program section of this Order, or \_\_\_\_\_.

(5) Comply with the same environmental release restrictions, if any, required of the Company in the Disposal and Release to Water sections of this Order, or \_\_\_\_\_.

(6) Not process the PMN substance:

- (i) In non-enclosed processes;
- (ii) At a site not in that person's control;
- (iii) Except as described in the PMN;
- (iv) In the form of a powder;
- (v) In the form of a solid;
- (vi) In the form of a liquid;
- (vii) In the form of a gas; or
- (viii) Other:\_\_\_\_\_.

(7) Not use the PMN substance:

- (i) At a site not under the person's control;
- (ii) In non-enclosed processes;
- (iii) Other than as an intermediate;
- (iv) Other than as a site-limited intermediate; or
- (v) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds \_\_\_\_\_percent;
- (vi) Other than as described in the PMN;

- (vii) For non-industrial applications;
- (viii) For commercial use;
- (ix) For non-commercial use;
- (x) In consumer products;
- (xi) In the form of a powder;
- (xii) In the form of a solid;
- (xiii) In the form of a liquid;
- (xiv) In the form of a gas;
- (xv) Involving an application method that generates a vapor, mist, or aerosol;
- (xvi) Involving an application method that generates a dust; or
- (xvii) Other: \_\_\_\_\_.

(ii) Disposal Exemption. Except for the §12(b) export notice requirement in paragraph (b)(i)(1) above, the distribution requirements in (b)(i) do not apply when the Company distributes the PMN substance for disposal only. **[Note to Program Managers: Delete this paragraph (ii) if the Consent Order contains disposal restrictions.]**

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the

Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

COMMENT 12/4/08 1:00 PM

**Comment:** [OR SPECIFY APPROPRIATE PROVISIONS, IF IT IS INAPPROPRIATE FOR ALL OF THE DISTRIBUTION PROVISIONS TO TERMINATE WHEN THE SNUR BECOMES EFFECTIVE]

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (b)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

COMMENT 12/4/08 1:00 PM

**Comment:** [OR SPECIFY APPROPRIATE PROVISIONS, IF IT IS INAPPROPRIATE FOR ALL OF THE DISTRIBUTION PROVISIONS TO TERMINATE WHEN THE SNUR BECOMES EFFECTIVE]

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (b)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice

COMMENT 12/4/08 1:00 PM

**Comment:** [OR SPECIFY APPROPRIATE PROVISIONS, IF IT IS INAPPROPRIATE FOR ALL OF THE DISTRIBUTION PROVISIONS TO TERMINATE WHEN THE SNUR BECOMES EFFECTIVE]

may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (b).

### **DISPOSAL**

(a) The Company shall dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

COMMENT 2/6/08 10:11 AM

**Comment:** [INCLUDE A PROVISION FROM THE DISPOSAL AND/OR RELEASE TO WATER SECTIONS IN ALL RISK-BASED ORDERS WITH ECOTOX RISK OR HUMAN HEALTH RISK FROM DRINKING WATER EXPOSURE.]

(1) The PMN substance must be disposed of only by:

- (i) incineration; \_\_\_\_\_
- (ii) landfill; \_\_\_\_\_
- (iii) deep well injection; \_\_\_\_\_
- (iv) other: \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a), (b), & (c)(1)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a), (b), & (c)(2)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a), (b), & (c)(3)]

(2) Waste streams from manufacture must be disposed of only by:

- (i) incineration; \_\_\_\_\_
- (ii) landfill; \_\_\_\_\_
- (iii) deep well injection; \_\_\_\_\_
- (iv) other: \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a)(1)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a)(2)]

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(a)(3)]

(3) Waste streams from processing must be disposed of only by:

- (i) incineration; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

**Comment:** - [721.85(b)(1)]

(ii) landfill; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(b)(2)]

(iii) deep well injection; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(b)(3)]

(iv) other: \_\_\_\_\_

(4) Waste streams from use must be disposed of only by:

(i) incineration; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(c)(1)]

(ii) landfill; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(c)(2)]

(iii) deep well injection; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(c)(3)]

(iv) other: \_\_\_\_\_

(5) The Company shall not dispose of or release the PMN substance into the environment. \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: . [721.85(d)]

### **RELEASE TO WATER**

(a) This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Company is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from \_\_\_\_\_ (manufacturing/processing/use) containing the PMN substance:

COMMENT 2/6/08 10:11 AM

Comment: [INCLUDE A PROVISION FROM THE DISPOSAL AND/OR RELEASE TO WATER SECTIONS IN ALL RISK-BASED ORDERS WITH ECOTOX OR HUMAN HEALTH RISK FROM DRINKING WATER EXPOSURE.]

(1) Into the waters of the United States; \_\_\_\_\_

COMMENT 2/6/08 10:11 AM

Comment: [TO COMPLETE THE BLANK SPACE IN THE FOLLOWING SNUR CITATIONS IN THIS RELEASE TO WATER SECTION, E.G. 721.90(\_\_\_\_)(1), INSERT "a" IN THE BLANK FOR RELEASES FROM MANUFACTURING, "b" FOR PROCESSING, AND "c" FOR USE.]

(2) Into the waters of the United States without application of one or more of the following specified treatment technologies either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

COMMENT 2/6/08 10:11 AM

Comment: . [721.90(\_\_\_\_)(1)]

(i) Chemical precipitation and settling; |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(i)]

(ii) Biological treatment (activated sludge or equivalent) plus clarification; |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(ii)]

(iii) Stream stripping; |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(iii)]

(iv) Resin or activated carbon adsorption; |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(iv)]

(v) Chemical destruction or conversion;

| (vi) Primary wastewater treatment; |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(v)]

(3) Into the waters of the United States without primary wastewater treatment, and

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](2)(vi)]

secondary wastewater treatment as defined in 40 CFR Part 133. |

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](3)]

(4)(i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ parts per billion}$$

exceeds \_\_\_\_\_, when calculated using the methods described in 40 CFR 721.91. | However, 40

COMMENT 2/6/08 10:11 AM

Comment: . [721.90( )](4)].

CFR 721.91(a)(4) does not apply. Instead, if the waste stream containing the PMN substance

will be treated using \_\_\_\_\_, then the amount of PMN substance reasonably likely to be

removed from the waste stream by such treatment may be subtracted in calculating the number

of kilograms released. No more than \_\_\_\_percent removal efficiency may be attributed to such

treatment. **[Note to Program Managers: Use this language, starting from “However, 40 CFR**

**721.91(a)(4) does not...” only when EPA has received and reviewed removal rate data..]**

When appropriate and EETD/EAB concurs, you may add the following language to the Order and SNUR:

However, contrary to 40 CFR 721.91(a)(4), if the waste stream containing the PMN substance will be treated using \_\_\_\_\_, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than \_\_\_\_ percent removal efficiency may be attributed to such treatment.

To convert this comment language to regular text: place the cursor after the comment, then press Ctrl-F5, 4, and 3.

(ii) In lieu of calculating the quotient in subparagraph (4)(i), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve

monitoring procedures or alternative calculations within 90 days after such a request is received.

The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

COMMENT 2/6/08 10:11 AM

Comment: - [721.90( ) (4)]

### III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

COMMENT 2/6/08 10:11 AM

Comment: [INCLUDE THOSE Record-keeping PROVISIONS WHICH CORRESPOND TO THE SUBSTANTIVE REQUIREMENTS IN THE BODY OF THE CONSENT ORDER. SUBPARAGRAPH (a)(1), PRODUCTION VOLUME, SHOULD BE INCLUDED IN ALL ORDERS WITH TESTING TRIGGERS AND/OR DISPOSAL OR RELEASE TO WATER RESTRICTIONS.]

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (3)

and (4) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) A copy of the Pollution Prevention Plan required by the Pollution Prevention Plan section of this Order;

(3) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

COMMENT 2/6/08 10:11 AM

Comment: [721.125(a) & (b)]

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(5) Records documenting the address of all sites of manufacture, import, processing, and use;

COMMENT 2/6/08 10:11 AM

Comment: [721.125(e)]

(6) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

COMMENT 2/6/08 10:11 AM

Comment: [721.125(d)]

(7) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(8) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

COMMENT 2/6/08 10:11 AM

Comment: [721.125(e)]

(9) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

COMMENT 2/6/08 10:11 AM

Comment: [721.125(f)]

(10) Copies of labels required under the Hazard Communication Program section of this

Order;|

COMMENT 2/6/08 10:11 AM  
Comment: . [721.125(g)]

(11) Copies of Material Safety Data Sheets required by the Hazard Communication

Program section of this Order;|

COMMENT 2/6/08 10:11 AM  
Comment: . [721.125(h)]

(12) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;|

COMMENT 2/6/08 10:11 AM  
Comment: [DELETE THOSE ACTIVITIES FOR WHICH THERE ARE NO CORRESPONDING SUBSTANTIVE REQUIREMENTS IN THE BODY OF THE ORDER]

(13) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;|

COMMENT 2/6/08 10:11 AM  
Comment: . [721.125(i)]

(14) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;|

COMMENT 2/6/08 10:11 AM  
Comment: . [721.125(k)]

(15) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(16) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured or imported;|

COMMENT 2/6/08 10:11 AM  
Comment: [NA]

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities

of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012**.

#### **IV. REQUESTS FOR PRE-INSPECTION INFORMATION**

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

- (i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;
- (ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;
- (iii) Current job titles or categories for workers who are involved in activities associated

with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

#### **V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER**

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the

Company (the “Successor in Interest”).

(b) Relation of Transfer Date to Notice of Commencement (“NOC”).

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import (“NOC”) for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) “Successor in Interest” means a person outside the Company who has acquired the Company’s full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) “Transfer Document” means the legal instrument(s) used to convey the interests in

the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the “Notice of Transfer” document which is incorporated by reference as Attachment D to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume (“test trigger”), the aggregate volume of the PMN substance manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

## **VI. MODIFICATION AND REVOCATION OF CONSENT ORDER**

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

**VII. EFFECT OF CONSENT ORDER**

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

---

Date

---

Jim Willis, Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

---

Date

---

Name:

Title:

Company:

## ATTACHMENT A

### DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

“Chemical name” means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service’s rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Chemical protective clothing” means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL RBH ORDERS WITH PROTECTIVE EQUIPMENT REQ'TS]

“Company” means the person or persons subject to this Order.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Commercial use” means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

COMMENT 2/14/08 11:10 AM  
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS WORD]

“Common name” means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Consumer” means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS WORD]

“Consumer product” means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS PHRASE]

“Container” means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Contract Manufacturer” means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS WITH CONTRACT MANUFACTURER PROVISIONS]

“Identity” means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Immediate use.” A chemical substance is for the “immediate use” of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Impervious.” Chemical protective clothing is “impervious” to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH ORDERS WITH DERMAL PROTECTION REQ'TS]

“Manufacturing stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH OR RBE ORDERS WITH DISPOSAL RESTRICTIONS]

“MSDS” means material safety data sheet, the written listing of data for the chemical substance.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“NIOSH” means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH ORDERS W/ RESPIRATOR REQ'TS]

“Non-enclosed process” means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH AND RBE ORDERS WITH MANUFACTURING, USE, OR DISTRIBUTION REQUIREMENTS CITING THIS PHRASE]

“Non-industrial use” means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH AND RBE ORDERS WITH MANUFACTURING, USE, OR DISTRIBUTION REQUIREMENTS CITING THIS PHRASE]

“PMN substance” means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS]

“Personal protective equipment” means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH ORDERS WITH PERSONAL PROTECTIVE EQUIPMENT REQ'TS]

“Process stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

COMMENT 2/14/08 11:10 AM  
Comment: [RBH AND RBE ORDERS WITH DISPOSAL RESTRICTIONS]

“Scientifically invalid” means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

COMMENT 2/14/08 11:10 AM  
Comment: [ALL ORDERS WITH TESTING TRIGGERS]

“Scientifically equivocal data” means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

COMMENT 2/14/08 11:10 AM

Comment: [ALL ORDERS WITH TESTING TRIGGERS]

“Sealed container” means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

“Use stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

COMMENT 2/14/08 11:10 AM

Comment: [RBH AND RBE ORDERS WITH DISPOSAL RESTRICTIONS]

“Waters of the United States” has the meaning set forth in 40 CFR 122.2.

COMMENT 2/14/08 11:10 AM

Comment: [RBH AND RBE ORDERS W/ RELEASE TO WATER PROVISIONS]

“Work area” means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

COMMENT 2/14/08 11:10 AM

Comment: [ALL ORDERS]

“Workplace” means an establishment at one geographic location containing one or more work areas.

COMMENT 2/14/08 11:10 AM

Comment: [ALL ORDERS]

## ATTACHMENT B

### STATISTICAL ANALYSIS OF NCELs ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

#### STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum (\bar{X}_{ij} - X_i)^2 / (n_i - 1), i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2) / (W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2 / [W_1^2 / (n_1 - 1) + W_2^2 / (n_2 - 1)]$$

where,

$$W_i = S_i^2 / n_i, i = 1, 2$$

$\bar{X}_1$  = Average of the results from the company laboratory

$\bar{X}_2$  = Average of the results from the independent laboratory

$n_1$  = Number of samples analyzed by the company laboratory

$n_2$  = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be an integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

<u>Data Set 1</u>		<u>Data Set 2</u>	
	80.56		97.11
	100.01		102.13
	86.04		99.83
	52.61		97.83
	84.85		105.44
	95.75		100.04
$\bar{X}_1 = 83.30$	$n_1 = 6$	$\bar{X}_2 = 100.40$	$n_2 = 6$
$S_1^2 = 278.72$	$W_1 = 46.25$	$S_2^2 = 9.26$	$W_2 = 1.54$
Absolute value of T = 2.467		f = 5.33	

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

<u>Data Set 1</u>	<u>Data Set 2</u>
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$$\begin{array}{llll}
 \bar{X}_1 = 95.37 & n_1 = 6 & \bar{X}_2 = 104.37 & n_2 = 6 \\
 S_1^2 = 65.59 & W_1 = 10.93 & S_2^2 = 27.25 & W_2 = 4.54 \\
 \text{Absolute value of } T = 2.290 & & f = 8.54 & 
 \end{array}$$

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

## **ATTACHMENT C**

### **POLLUTION PREVENTION PLAN GUIDANCE**

This attachment provides non-binding guidance to assist the Company in the preparation of its Pollution Prevention Plan for the PMN substance. There are three parts to this attachment. Part 1 provides a list of suggested contents for the Pollution Prevention Plan. Part 2 is a checklist of possible process options that the Company may wish to consider and evaluate in developing its Pollution Prevention Plan. Part 3 is a list of pollution prevention reference materials.

The standardized guidance in this attachment is intended to facilitate understanding and ease of processing for both the Company's development and use of the Pollution Prevention Plan and EPA's review and use of that information. However, the guidance in this attachment is recommended but not legally required. The Company is permitted to submit a Pollution Prevention Plan using other formats and contents, particularly any specified by state law. As experience is gained over time, EPA may modify these guidance materials. EPA welcomes comments regarding the guidance materials in this attachment.

Part 1 -- Suggested Contents of Pollution Prevention Plan.

The Pollution Prevention Plan may contain the following information:

1. Executive Summary. A short paragraph highlighting significant aspects of the Pollution Prevention Plan. Summarize the sources of the releases and exposures of the PMN substance. Summarize the risk reduction actions selected for implementation in the Company's process for handling the PMN substance and the rationale for such selections. Compare the releases and exposures for the various process options considered. Discuss how the Company's process for handling the PMN substance applies the environmental management hierarchy articulated in the Pollution Prevention Act of 1990 (42 USC 13101) and EPA's Pollution Prevention Strategy (56 FR 7849; Feb. 26, 1991). Summarize the same information in relation to subsequent recipients of the PMN substance. If the Company's Executive Summary contains confidential business information ("CBI"), the Company should also submit a sanitized version of the Executive Summary from which all CBI has been removed.
2. SIC Code. The four-digit Standard Industrial Classification code(s) that best describes the industry segment(s) referenced in the plan.
3. Name & Location of Facilities. The name and location of the facilities identified in the plan. Include addresses if possible.
4. Company Contact Person (if different from that in the PMN submission). Name of contact, telephone number and address. The contact should be a person who can answer technical questions regarding the Pollution Prevention Plan.
5. Description of Risk Reduction Options Considered. Describe, in the order of the environmental hierarchy articulated in the Pollution Prevention Act of 1990 and EPA's Pollution Prevention Strategy, the risk reduction options considered for the Company's own processes for handling the PMN substance as well as for subsequent distributees. A sample list of potential process options that the Company may wish to consider is provided in Part 2 of this attachment.
6. Discussion of Risk Reduction Actions Selected for Implementation. Identify the risk reduction actions selected (at the Company's discretion) for implementation in the Company's processes for handling the PMN substance, as well as risk reduction actions recommended by the Company for its subsequent distributees, as a result of developing the Pollution Prevention Plan and the rationale for such selections. Compare the releases and exposures for the various process options considered. Discuss how the Company's process for the PMN substance applies the pollution prevention hierarchy articulated in the Pollution Prevention Act of 1990 and EPA's Pollution Prevention Strategy.  
*Include any relevant supporting information, such as experimental design data and equipment description.*
7. Anticipated Reductions in Releases and Exposures.

(a) Compare the environmental releases and worker exposures of the PMN substance from the various process options considered. If the following process options differ, include the process described in the PMN, the process implemented after expiration of the 90-day PMN review period but before development of the Pollution Prevention Plan, and the process selected for implementation from the Pollution Prevention Plan. Include any relevant supporting information, such as test data and detailed process flow diagrams.

(i) Include a block flow diagram for each of the process options considered, identifying (by letters or numbers) all the PMN process streams and waste streams. Provide a brief description of each of the processes. Highlight unique aspects of the actions selected for implementation.

(ii) For each stream containing the PMN substance, provide a table (such as the table below, for example, or another format where appropriate) summarizing the stream's: identity (release point); type (process or waste, including releases from container residue and cleanup operations); total mass; total mass of PMN substance; media (gas, solid, liquid); composition (i.e., identity and relative percentage of chemical components); treatment technology (e.g., flare, scrubber, dust collector, incineration); treatment efficiency; disposal method (e.g., landfill, underground injection); and frequency of release. Treatment technology, treatment efficiency, disposal method, and frequency of release apply only to waste streams.

(iii) Provide a mass balance for each process option considered (per batch, or per unit time if the process is continuous), number of batches per shift, number of shifts per day of operation, and the number of days of operation per year.

Stream	A	B	C	D
Stream Type				
Total Mass of Stream (kg)				
Total PMN Mass (kg)				
Media				
Chemical X Weight %				
Chemical Y Weight %				
Chemical Z Weight %				
Treatment Technology				
Treatment Efficiency (% removal)				
Disposal Method				
Frequency of Release				

(iv) For each process option considered, provide a table (such as the table below, for example) summarizing the worker exposures.

Worker Activity	Total # Workers Potentially Exposed	Duration of Exposure (hours/day and days/yr)	Protective Equipment/ Engineering Controls	% PMN in Formulation

## Part 2 - Checklist of Possible Process Options for Pollution Prevention Plan.

The following is a checklist of possible process options and other factors that the Company may wish to consider and evaluate in developing its Pollution Prevention Plan:

1. Characterization of all release points and fugitive emissions to identify pollution prevention opportunities -----> source reduction, recycling/reuse, treatment, disposal.

Perform material balances for the manufacturing, processing, and use operations. The material balances should identify all the PMN and associated existing chemical waste streams from the various processes. Complete material balances and/or material balances of each major unit operation may be necessary to address EPA's concerns.

A summary of the waste streams and potential pollution prevention options to reduce these wastes would be very helpful. The summary should also include information on the point of generation, release quantity, media of release (air, land, water) and pollution prevention considerations for these waste streams.

2. Process Chemistry-----> Source Reduction

Describe the chemical approaches used to minimize waste production, including the following considerations.

- (a) Selection of synthetic method: high yield, minimal side reactions, no coproducts unless they are commercialized or otherwise used
- (b) Choice of feedstocks, reagents, solvents, etc.
- (c) Purity of feedstocks, reagents, solvents, etc.

- (d) Optimization of reaction conditions to minimize side reactions
- (e) Product purification
- (f) Optimization of stoichiometry to minimize presence of excess reactants
- (g) Use of advanced chemical technology such as shape-selective zeolite catalysts, stereoselective synthesis, and permselective membranes for molecular separations (liquid phase).

### 3. Product Substitution-----> Source Reduction

If appropriate, analyze perceived advantages or disadvantages of the new chemical substance compared to other existing substances and compare the relative risks of the substances. A new chemical that performs the same function as an existing chemical may produce less pollution, but may be much more toxic and therefore cause greater risk.

If appropriate, investigate potential changes in product composition or physical state to reduce waste and emissions. For example: 1) using a more concentrated product may decrease the amount of waste generated, and 2) reformulating a powder into a paste may mitigate inhalation concerns.

### 4. Process Modifications-----> Source Reduction

#### (a) Engineering Technology Changes

In many cases, the PMN chemicals may be produced using existing equipment which may not be the best technology from the pollution prevention standpoint. Investigate alternative technologies for major unit operations (e.g., phase separation, filtration) in the processes and their impacts on waste and emissions generation. Some examples of alternative technologies include: steam stripping versus air stripping, pan filter versus rotary drum filter or centrifuge, flash dryer versus spray dryer.

#### (b) Equipment/Piping/Layout Changes

Investigate potential equipment/piping/layout alternatives and their impacts on waste and emissions generation. Some examples of these changes include: 1) redesigning equipment and piping to reduce the volume of material drained for batch changes or for cleaning operations, and 2) installing bellows-sealed valves versus conventional valves to reduce VOC emissions.

## (c) Operating Conditions

Optimize operating conditions at major unit operations (including reactors and separation equipment). Also, available supporting laboratory information (i.e. experimental design data) should be collected and analyzed.

## (d) Automation

Identify potential automation/control steps which may have pollution prevention implications. For example, a batch process may be successfully automated to reduce off-spec product and spillage, which reduces waste.

## 5. Operating Practices-----&gt; Source Reduction

Identify various operational and administrative changes to prevent pollution. Examples of categories of operational and administrative changes are:

## (a) Procedural Measures

For example, increasing drain time from 15 minutes to 20 minutes could reduce leftover material in a tank.

## (b) Loss Prevention

Installing overflow alarms in tanks could reduce overflows or releases.

## (c) Management Practices

Reducing inventories of toxics could minimize the consequences of emergencies.

## (d) Waste Stream Segregation

Segregating waste streams to avoid cross contaminating hazardous and non-hazardous materials could allow in-process recycling of some of the waste.

## (e) Material Handling Improvements

Changing from small-volume containers to bulk or reusable containers could reduce releases of residue.

## (f) Production Scheduling

Making large batches of a similar paint formulation instead of small batches of different paint formulation could reduce cleanup waste.

## 6. Reuse and Reclamation-----> Recycling/Reuse

Identify potential recycling/reuse (on-site and off-site) opportunities of the waste streams (identified in 2 above). Examples of recycling/reuse opportunities are:

### (a) Materials Returned to Original Process

For example, returning recovered solids from a filtrate (through the use of a settling tank) to the reactor.

### (b) Materials Processed for Resource Recovery

For example, installing vapor recovery systems to capture and return vaporous emissions.

### (c) Materials Processed as a By-product

For example, the off-acid gas from a reactor could be absorbed with water to convert it into dilute acid and sold as a by-product.

## 7. Energy

Analyze anticipated impacts on energy use. Almost any change to an industrial or commercial process will entail some change in the amount and form of energy consumed in that process.

Energy conservation is a form of pollution prevention. For example, reduced energy use decreases the quantity of fossil fuels burned and thus the the amount of environmental damage from resource extraction and amount of air pollutants generated. Reduced boiler operation reduces the discharge of waste cooling water blow down and boiler blowdown. Purification of raw water to produce boiler feedwater requires purification of raw water by ion exchange or other processes. These treatments produce wastes, such as treatment chemicals. Reduced energy consumption also reduces these waste streams.

## 8. Changes in Treatment Methods -----> Treatment

Investigate alternative treatment methods and compare treatment efficiency and multimedia (land, air, water) releases. The analysis should include information on the compositions and quantities of all the input PMN waste streams and output release streams.

#### 9. Waste Disposal-----> Disposal

Analyze the PMN waste streams being disposed. The analysis should include information on the quantity and media of release, compositions of the waste, and the regulatory limits applicable to each of the waste streams being disposed.

#### 10. Material Balance Comparison of Various Process Options

Compare material balances of the various process options considered. If the following process options differ, include the process described in the PMN, the process implemented after expiration of the 90-day PMN review period but before development of the Pollution Prevention Plan, and the process selected for implementation from the Pollution Prevention Plan.

#### 11. Reduction in Worker Exposures

Compare worker exposures of the various process options considered. If the following process options differ, include the process described in the PMN, the process implemented after expiration of the 90-day PMN review period but before development of the Pollution Prevention Plan, and the process selected for implementation from the Pollution Prevention Plan. The comparison should include information on the worker activities, # of workers exposed, # hours exposed/day, # days exposed/year, protective equipment or engineering controls, % PMN substance in formulation, route of exposure (i.e. inhalation, dermal), and media of release (solid, vapor, liquid).

#### 12. Cost/Benefit Analysis

Compare the estimated costs and benefits of the process options considered. If the following process options differ, include the process described in the PMN, the process implemented after expiration of the 90-day PMN review period but before development of the Pollution Prevention Plan, and the process selected for implementation from the Pollution Prevention Plan.

**ATTACHMENT D**

**NOTICE OF TRANSFER  
OF  
TOXIC SUBSTANCES CONTROL ACT  
SECTION 5(e) CONSENT ORDER**

\_\_\_\_\_  
Company (Transferor)

\_\_\_\_\_  
PMN Number

1. Transfer of Manufacture Rights. Effective on \_\_\_\_\_, the Company did sell or otherwise transfer to \_\_\_\_\_, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

\_\_\_ reasserts,

\_\_\_ relinquishes, or

\_\_\_ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

**TOXIC SUBSTANCES CONTROL ACT  
SECTION 5(e) CONSENT ORDER**

**NOTICE OF TRANSFER  
(continued)**

\_\_\_\_\_  
**Company (Transferor)**

\_\_\_\_\_  
PMN Number

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Authorized Official

\_\_\_\_\_  
Title of Authorized Official

\_\_\_\_\_  
**Successor in Interest**

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Authorized Official

\_\_\_\_\_  
Title of Authorized Official

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip Code

**TOXIC SUBSTANCES CONTROL ACT  
SECTION 5(e) CONSENT ORDER**

**NOTICE OF TRANSFER  
(continued)**

---

**Successor's Technical Contact**

---

Address

---

City, State, Zip Code

---

Phone

## APPENDIX 1

### LIST OF RESPIRATORS

**Note to Program Managers:** Copy the respirators in the appropriate exposure category below, then paste that information into the Protection in the Workplace section (a)(6) of the Consent Order (found in the boilerplate on page 13). For example, if the exposure to the PMN substance is expected to be in particulate form, copy all of the information in the “Particulate/Aerosol/Mist Exposure” category for the APF you need below. After you have inserted the information into the Consent Order, delete this Appendix 1.

Delete irrelevant respirators by unit, e.g. Particulate, APF of 2 to 10. Each unit is separated by a line divider ( \_\_\_\_\_ ) and has a heading in red bold. Do *not* copy the line dividers or red bold headings into the body of the Order. Adjust numbering as necessary in the Order. Each unit does not require any editing unless specified.

---

#### **Particulate, APF of 2 to 10**

(i) Particulate/Aerosol/Mist Exposures, APF of 2 to 10:

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, delete this respirator.]**

(II) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (“HEPA”) filters.

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program**

**Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Particulate, APF of 11 to 25**

(i) Particulate/Aerosol/Mist Exposures, APF of 11 to 25:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(II) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and HEPA filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Particulate, APF of 26 to 50**

(i) Particulate/Aerosol/Mist Exposures, APF of 26 to 50:

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(II) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Particulate, APF of 51 to 2000**

(i) Particulate/Aerosol/Mist Exposures, APF of 51 to 2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

---

**Gas/Vapor, APF of 2 to 10**

(ii) Gas/Vapor Exposures, APF of 2 to 10:

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by*

*EPA:*

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-

specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, this option should be deleted.]**

(II) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(III) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(VI) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose fitting hood or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Gas/Vapor, APF of 11 to 25**

(ii) Gas/Vapor Exposures, APF of 11 to 25:

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by*

*EPA:*

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(II) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(III) NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose-fitting hood or helmet or a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Gas/Vapor, APF of 26 to 50**

(ii) Gas/Vapor Exposures, APF of 26 to 50:

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by*

*EPA:*

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

(II) NIOSH-certified powered air-purifying, tight-fitting respirator (either half-face or full-face) equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face).

**[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.

---

**Gas/Vapor, APF of 51 to 2000**

(ii) Gas/Vapor Exposures, APF of 51 to 2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

---

**Combination Gas/Particulate, APF of 2 to 10**

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 2 to 10:

**If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:**

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, this option should be deleted.]**

(II) NIOSH-certified air-purifying, tight-fitting full facepiece respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(III) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges.

Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(VI) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Combination Gas/Particulate, APF of 11 to 25**

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 11 to 25:

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(II) NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Combination Gas/Particulate, APF of 26 to 50**

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 26 to

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by*

*EPA:*

(I) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

(II) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

(III) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

*If No Cartridge Service Life Testing is Available:*

(IV) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If a concern exists for irritation to the eyes, mucous membranes, or skin, the half-face piece should be deleted.]**

---

**Combination Gas/Particulate, APF of 51 to 2000**

(iii) Combination of Gas/Vapor and Particulate (paint spray, etc.), APF of 51 to

2000:

(I) NIOSH-certified supplied-air respirator operated in pressure demand

or other positive pressure mode and equipped with a tight-fitting full facepiece.

COMMENT 2/14/08 11:22 AM

Comment: - [721.63(a)(5)(xv)]

## APPENDIX 2

### NCELS RESPIRATOR TABLES Measured Concentrations of PMN Substance and Corresponding Acceptable Respiratory Protection

**Note to Program Managers:** Copy the appropriate respirator table below and paste into the NEW CHEMICAL EXPOSURE LIMIT section (e)(2) of the Consent Order. After copying the table into the Order, adjust the line spacing so that the table is single spaced and the rest of the Order is double spaced. **After you have copied and pasted the table into the Consent Order, delete this Appendix 2.**

#### PARTICULATE RESPIRATOR TABLE

##### Measured Concentration of PMN Substance

##### Required Respiratory Protection

$\leq$  NCEL

- ▶ No respiratory protection is required.

$\leq 10 \times$  NCEL

- ▶ NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
- ▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.
- ▶ NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters.
- ▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**



$\leq 25 \times \text{NCEL}$	<ul style="list-style-type: none"> <li>▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.</li> <li>▶ NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and HEPA filters.</li> <li>▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters.  <b>[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]</b></li> <li>▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face). <b>[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]</b></li> </ul>
$\leq 50 \times \text{NCEL}$	<ul style="list-style-type: none"> <li>▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.</li> <li>▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters.  <b>[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]</b></li> <li>▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (either half-face or full-face). <b>[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]</b></li> </ul>
$\leq 2000 \times \text{NCEL}$	<ul style="list-style-type: none"> <li>▶ NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.</li> </ul>
$> 2000 \times \text{NCEL}$	<ul style="list-style-type: none"> <li>▶ Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.</li> <li>▶ Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.</li> </ul>

### **GAS/VAPOR RESPIRATOR TABLE**

**Measured  
Concentration  
of PMN Substance**

**Required Respiratory Protection**

≤ NCEL

- ▶ No respiratory protection is required.

≤ 10 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and  
Approved by EPA:*

- ▶ NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
- ▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
- ▶ NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
- ▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose fitting hood or tight-fitting facepiece (either half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

≤ 25 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

- ▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
- ▶ NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
- ▶ NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half-face or full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**
- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose-fitting hood or helmet or a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

≤ 50 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

- ▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
- ▶ NIOSH-certified powered air-purifying, tight-fitting respirator (either half-face or full-face) equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

- ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.
- ≤ 2000 x NCEL ▶ NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.
- > 2000 x NCEL ▶ Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.
- ▶ Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

**COMBINATION PARTICULATE AND GAS/VAPOR RESPIRATOR TABLE**

**Measured  
Concentration  
of PMN Substance**

**Required Respiratory Protection**

- ≤ NCEL ▶ No respiratory protection is required.

- ≤ 10 x NCEL *If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

- ▶ NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

► NIOSH-certified air-purifying, tight-fitting full facepiece respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

► NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

► NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

► NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

► NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

≤ 25 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

► NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

► NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and the appropriate combination cartridges.

Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters.

► NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

► NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

► NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (half-face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

≤ 50 x NCEL

*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

► NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100).

► NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and the appropriate combination cartridges. Cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include HEPA filters. **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

► NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-

face or full-face). **[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]**

*If No Cartridge Service Life Testing is Available:*

- |  |   |
|--|---|
| ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (half-face or full-face). <b>[Note to Program Managers: If an exposure concern exists for the eyes or skin, delete this option.]</b> |   |
| <b>≤ 2000 x NCEL</b>   | ▶ NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.   |
| <b>&gt; 2000 x NCEL</b>  | <p>▶ Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.</p> <p>▶ Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.</p> |